

REMARKS

Claims 3-11, 16, 17 and 25-52 are pending in the application. Claims 3-11, 16, 17 and 25-39 have been withdrawn from consideration. Claims 40-52 have been rejected.

Sequence Listing

The Examiner has stated that the C.F.R. submitted by the Applicants includes an error which requires the appropriate correction. In response, Applicants herewith provide a new sequence listing and C.F.R. containing all the sequences. Applicants now submit that they comply with the requirements with the sequence rules of 37 C.F.R. §§ 1.81-1.825.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 40-52 of the present application under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner points to the phrase "each bond between two amino acids, or amino acid derivatives, represented by a dash ("-"), can be either a peptide bond or a pseudopeptide bond". The Examiner objects to this term as rendering the claim indefinite because "it is not clear how a bond between two amino acids can be a pseudopeptide". Applicants respectfully disagree.

Applicants assert that it is known to those of skill in the art that a pseudopeptide bond may be present between amino acids. Further, Applicants assert that the chemistry of pseudopeptide bonds is disclosed in the present application. In particular, these structures, including examples, are disclosed in the specification at least at page 11, beginning at line 19; page 16, beginning at line 7; and page 37, beginning at line 12. Further, Applicants submit that Coy et al., "Solid Phase Reductive Alkylation Techniques in Analogue Peptide Bond and Side-Chain Modification", *Tetrahedron*, Vol. 44, No. 3, pgs. 835-841, which was incorporated by reference into the present application, also discloses the modification of the peptide bond CONH group, in order to alter a peptide conformation by reducing that peptide bond to CH₂NH group, for example. Further, standard nomenclature, as is known to those of skill in the art, allows for pseudopeptide bonds between two amino acids. The nomenclature of pseudopeptides is compatible with the standard three-letter amino acid designation. For example, considering a Tyr-Ala designation for the dipeptide sequence tyrosinylalanine, the hyphen is known to represent the peptide bond. But there is no peptide bond between two amino acids in the case of pseudopeptides; therefore, the hyphen is not used. As described throughout the specification, the symbol "Ψ[]" is used in pseudopeptides instead of the hyphen, and the structure that replaces the peptide bond is specified within the brackets. Thus, TyrΨ[CH₂NH]Ala represents pseudodipeptide with the carbonyl of the peptide bond, CONH group, replaced with the methylene group, CH₂, and the nitrogen replaced with NH.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected claims 40 and 43 under 35 U.S.C. § 102(b) as being anticipated by Koenig et al., EP 288965 (the Koenig '965 patent). In particular, the Examiner states that the Koenig '965 patent teaches a peptide having a formula of L-B-A, wherein the N-terminal group can be benzyloxycarbonyl or (C₁-C₄)-alkylcarbonyl, L is a lipophilic residue such as Leu and Trp, B is basic residue such as Orn and Cit, and A is an aromatic residue such as Trp. In particular, the Examiner notes that each of these residues are also disclosed in the formula of the present invention claimed in claim 40.

In order to overcome this rejection, Applicants have amended claim 40 to note that a therapeutically effective amount of the compound is present in combination with a pharmaceutically acceptable carrier substance in order to provide a composition capable of attenuating NPY mediated or NPY-like physiological responses. Support for this amendment can be found in claim 46, which was not rejected by the Examiner under §102 in view of the Koenig '965 patent. Applicants submit that the Koenig '965 patent does not teach such a composition as recited in presently amended claim 40. Applicants thus submit that claim 40, as presently amended, is not anticipated by the Koenig '965 patent, and thus respectfully requests withdrawal of this rejection.

Conclusion

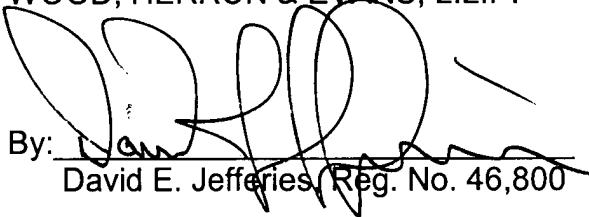
For the foregoing reasons, Applicants submit that all claims are patentable and a Notice of Allowance is respectfully requested.

Applicants believe that no fee is due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

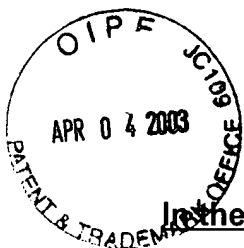
The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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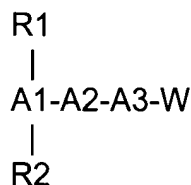
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In the claims:

40. (TWICE AMENDED) A therapeutic composition comprising:

a therapeutically effective amount of a [A] compound having the formula:



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wherein:

each R1 and R2, independently, is H, C1-C12 alkyl, C6-C18 aryl, C1-C18 acyl, C7-C18 aralkyl, C7-C18 alkaryl or a dihydrotrigonellinate group;

A1 is a D or L-amino acid selected from the group consisting of Cys, Leu, Dap, Trp, Gln, a tethered amino acid with an indole ring, Phe, Hyp, a derivative of Trp selected from the group consisting of N-Me-Trp, nor Trp, beta Me-Trp, 2-Cl-Trp, and 5-X-Trp where X is selected from the group consisting of CN, Br, NH₂, COOH, CH₂NH₂ and CH₂-CH₂NH₂; CαMe-Trp, CαMe-Gln, Des-amino-Trp, Pyr, Bth, Nal, Tcc, Asn, Nva, Abu, Tyr, Tic-OH, Phe, Tip, and Dip;

A2 is a D or L-amino acid selected from the group consisting of Cys, Trp, Arg, Nα-Me-Arg, CαMe-Arg, Orn, Cit, hArg(R)₂, where R is selected from the group consisting of hydrogen, alkyl, aryl, aralkyl, or alkylaryl, Lys-ε-NH-R, where R is selected from the group consisting of alkyl, aryl, aralkyl, or alkylaryl; A3 is a D or

L-amino acid selected from the group consisting of Glu, N-Me-Tyr, C α Me-Tyr, Tic-OH, Tic, Dip, Trp, Phe, des-carboxylic-Tyr (tyramine), and Tyr-(R), where R is hydrogen or a lipophilic group;

W is -OH, -N-R₃R₄, or OR₅, where R₃, R₄, and R₅, independently, is H, C₁-C₁₂ alkyl, C₆-C₁₈ aryl, C₁-C₁₂ acyl, C₇-C₁₈ aralkyl, or C₇-C₁₈ alkaryl, or a pharmaceutically acceptable salt thereof; and

each bond between two amino acids or amino acid derivatives, represented by a dash ("-"), can be either a peptide bond or a pseudopeptide bond[.] ; and

a pharmaceutically acceptable carrier substance;

said composition being capable of attenuating Neuropeptide Y (NPY) mediated or NPY-like physiological responses.

47. (AMENDED)The composition of claim [46] 40, wherein said composition is in the form of a pill, tablet, or capsule for oral administration.

48. (AMENDED)The composition of claim [46] 40, wherein said composition is in the form of a liquid for oral administration.

49. (AMENDED) The composition of claim [46] 40, wherein said composition is in the form of a liquid for nasal administration as drops or spray.

50. (AMENDED)The composition of claim [46] 40, wherein said composition is in the form of a liquid for intravenous, subcutaneous, parenteral, or intraperitoneal administration.

51. (AMENDED)The composition of claim [46] 40, wherein said composition is in the form of a biodegradable sustained- release composition for intramuscular administration.

52. (AMENDED)The composition of claim [46] 40, wherein said composition includes a lipophilic salt and is suitable for administration in the form of an oil emulsion or dispersion.

Claim 46 has been deleted.